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Section 3: 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA I990 and 21 CFR §807.92.

510k: K123582

1. **Submitter's Identification:**

Saeyang Microtech Co., Ltd.
100-39 Galsan-Dong, Dalseo-Gu,
Daegu, Korea
Phone: 82-53-582-9000-2
Fax: 82-53-581-9003
Contact – Kim San-ghoon

AUG 16 2013

Date Summary Prepared: July 12, 2013

2. **Name of Device:**

Trade/Proprietary Name:
ENDO a class

Classification Name:
Handpiece, direct drive, ac-powered

Class in which Device has been placed:

The Dental panel has classified this device as Class I, 21 CFR Part 872.4200, Product Code EKX.

3. **Predicate Device Information:**

1. K092833 Dentamerica Inc Cordless Endodontic Handpiece
2. K970339 J. Morita USA, Inc Tri Auto Zx

3. 090931 W & H Dentalwerk GMBH Cordless ENDO handpiece ENTRAN

4. **Device Description:**

The motor turned by the power converted into DC2.4V by controller delivers its turning power to the file through spin to perform punching, cutting and removing functions. The hand-piece can be operated, stopped and set/adjusted on/in its speed, torque and turning direction by handling of the controller.

5. **Indication for Use:**

This application area extends to endodontic procedures using a root canal instrument which is intended by the manufacturer for use in the mechanical and rotary preparation of root canals.

6. **Substantial Equivalence:**

The ENDO a class has similar characteristics and intended use as previously cleared devices. The subject device is substantially equivalent to the predicate devices.

	Device	**Predicate 1**	**Predicate 2**	**Predicate 3**
510(k) Number		K092833	K970339	K090931
Device Name	ENDO a Class	Endo-max	Tri Auto ZX	ENTRAN & S5 ENDO Motor
Common Name	Cordless Endodontic Handpiece	Cordless Endodontic Handpiece	cordless endodontic treatment motorized handpiece with root canal measurement	Cordless ENDO-Handpiece "ENTRAN"
Manufacturer	Saeyang Microtech	Dentamerica Inc.	J.Morita USA Inc.,	W&H
Intended Use	This application area extends to endodontic	This application area extends	The TRI AUTO ZX device is a	Modular electrical system for mechanical

	procedures using a root canal instrument which is intended by the manufacturer for use in the mechanical and rotary preparation of root canals.	to endodontic procedures using a root canal instrument which is intended by the manufacturer for use in the mechanical and rotary preparation of root canals.	cordless endodontic treatment motorized handpiece with root canal measurement capability. It can be used to enlarge canals while monitoring the position of the file tip inside the canal. It can be used to measure the length of the canal, and it can be used as a low speed motorized handpiece.	preparation of the root canal, using a special root canal instrument(END O file), which is intended by the manufacturer for use in the mechanical and rotary preparation of the root canal.
Allows adjustment of the motor speed	140~500rpm	125~625rpm	280rpm	300rpm
Allows setting the torque applied to the motor in Ncm	0.1-4.0 Ncm	1.0-5.0 Ncm	Low mode or High mode	0.5~4.0 Ncm
Allows selection of gear ratios for different geared E-type handpieces	4:1, 10:1, 16:1, 20:1	17:1	32:1	16:1
Allows selection of forward or Auto reverse drive rotation	YES	YES	YES	YES

Allows reciprocation drive(forward/reverse cycling)	YES	YES	YES	YES
Allows the user to define their own presets for speed and torque	YES	YES	YES	YES
Auto Power Off	YES	YES	YES	YES
Product material	-Injection Molding(ABS) -Screw cap & o-ring(silicon) -machine work(Kind of SUS)	-Injection Molding(ABS) -Screw cap & o-ring(silicon) -machine work(Kind of SUS)	-Injection Molding(ABS) -Screw cap & o-ring(silicon) -machine work(Kind of SUS)	-Injection Molding(ABS) -Screw cap & o-ring(silicon) -machine work(Kind of SUS)
Principle of Operation	The motor turned by the power converted into DC2.4V by controller delivers its turning power to the file through spin to perform punching, cutting and removing functions. The hand-piece can be operated, stopped and set/adjusted on/in its speed, torque and turning direction	The motor turned by the power converted into DC3.6V by controller delivers its turning power to the file through spin to perform punching, cutting and removing functions. The hand-piece can be operated, stopped and set/adjusted on/in its speed, torque and turning	The motor turned by the power converted into DC3.6V by controller delivers its turning power to the file through spin to perform punching, cutting and removing functions. The hand-piece can be operated, stopped and set/adjusted on/in its speed, torque and turning	The motor turned by the power converted into DC2V by controller delivers its turning power to the file through spin to perform punching, cutting and removing functions. The hand-piece can be operated, stopped and set/adjusted on/in its speed, torque and turning direction by handling of the controller

	by handling of the controller	direction by handling of The controller	direction by handling of the controller	
Input voltage(charger)	AC100V~240V	AC100V~240V, 50-60Hz	AC110V or 220V, 50-60Hz	AC100V~240V, 50-60Hz
Rechageble Battery	Ni_Mh 1.2V*2	Li_ion 3.7V	Ni_Mh 1.2V*3	Li_ion 3.7V
Motor Voltage	DC2.4V	DC3.6V	DC3.6V	DC2V
Motor Size	13 ¢ * 31.5(L)	13 ¢ * 31.5(L)	13 ¢ * 31.5(L)	13 ¢ *31.5(L)
Demensions(Handpiece)	192(L) X 27(W) X 28(H)	192(L) X 26(W) X 29(H)	193(L) X 30(W) X 37(H)	187(L) X 28(W) X 26(H)
Weight(Handpiece)	138g	150g	130g	120g
Demensions(charging station)	115(L) X 98(W) X 60(H)	105(L) X 85(W) X 59(H)	123(L) X 88(W) X 55(H)	160(L) X 95(W) X 62(H)

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Testing that was conducted in accordance with IEC 60601-1: 1988 +A1 1991,+A2 1995; ANSI/AAMI/IEC 60601-1-2: 2007;
Non-clinical Bench Test performed as following:

Test Standards	Result
ISO3964:1982	Complied
ISO7494-1:2004	
ISO7785-2:1995	
ISO11498:1997	

Along with the above tests, sterilization validation, software validation, speed accuracy testing, and temperature rise testing were also conducted.
None of the testing demonstrated any design characteristics that violated the requirements of the standards or resulted in any safety hazards.

7. Discussion of Clinical Tests Performed:

No clinical testing was conducted.

8. Conclusions:

The ENDO a class is substantially equivalent to the predicate in intended use, operation, safety and function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 16, 2013

Saeyang Microtech Company, Limited
C/O Mr. Jigar Shah
Official Correspondent
MDI Consultants, Incorporated
55 Northern Boulevard
GREAT NECK NY 11021

Re: K123582
Trade/Device Name: ENDO a Class
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EKX
Dated: July 12, 2013
Received: July 18, 2013

Dear Mr. Shah:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Section 2: Indications for Use

510(k) Number (if known): K123582

Device Name: ENDO a class

Indications For Use:

This application area extends to endodontic procedures using a root canal instrument which is intended by the manufacturer for use in the mechanical and rotary preparation of root canals.

Prescription Use X (Per 21 CFR 801 Subpart D) OR **Over-The Counter Use** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheena A. Green -S
2013.08.16 09:23:32 -04'00'
for M. Susan Runner, DDS, MA

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K123582